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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/731,699  | 12/09/2003  | Darren A. Janzig     | 1023-331US01        | 3259             |
| 28863   | 7590        | 12/15/2005           | EXAMINER            |                  |
| SHUMAKER & SIEFFERT, P. A.<br>8425 SEASONS PARKWAY<br>SUITE 105<br>ST. PAUL, MN 55125 |             |                      | GREENE, DANA D      |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3762                |                  |

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Tolch

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/731,699             | JANZIG ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Dana D. Greene         | 3762                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 9/26/05.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-15 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-15 and 17-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/9/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/29/05</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

Claims 1, 3-15, and 17-23 remain rejected under the same references disclosed in the Office Action mailed June 24, 2005. The cancellation of claims 2 and 16 have been noted along with the addition of claims 24 and 25. The examiner has given full consideration to the Applicant's response filed on September 26, 2005. However, Applicant's arguments and amendments are not persuasive and do not overcome the original rejection.

The examiner has alleged a prima facie case of anticipation with respect to claims 1, 3, 7, 8, 11, 12, and 14-23 and the examiner cites Wirtzfeld et al. (US 4,399,820, hereinafter "Wirtzfeld"). Further, claim 6 remains unpatentable over Wirtzfeld in view of Reischl et al. (US 6,176, 879 B1, hereinafter "Reischl"). Claims 4 and 9-10 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Wirtzfeld in view of Bradley (US 6,490,486 B1, hereinafter "Bradley"). Claim 13 remains rejected under 35 U.S.C. §103(a) as being unpatentable over Wirtzfeld in view of Schroepel (US 5,776,169, hereinafter "Schroepel"). Finally, new claims 24 and 25 are rejected under 35 U.S.C. §102(b) as being anticipated by Wirtzfeld.

Examiner has cited areas of Wirtzfeld; which show a pacer module and a sensor module separated by a lead with a lumen. The examiner has pointed to the specific sites in Wirtzfeld and Reischl that they be combined in the manner suggested. With this suggestion, it would have been obvious to one of ordinary skill in the art to combine the teachings of Wirtzfeld with Reischl for the purpose

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of reducing the size of the implantable medical device and reducing limits on the locations within the human body in which the IMD can be practically implanted.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 7, 8, 11, 12, 14-25 stand rejected under 35 U.S.C. §102(b) as being anticipated by Wirtzfeld. Wirtzfeld is considered to disclose:

a least two modules, each of the modules comprising a respective one of at least two housings (see col. 4, ln. 5-20, Wirtzfeld). The disclosed pacemaker and measuring probe are considered to anticipate the claimed modules because the pacemaker and measuring probe receive power or signals from one another in the same manner that the modules receive power or signals from each other;

a coupling module coupled to each of the modules, the coupling module defining at least one lumen between the housings,

an overmold that at least partially encapsulates each of the housing and the coupling module (see col. 4, ln. 64-68, Wirtzfeld).

wherein the coupling module permits motion of the two modules along at least one axis of motion (see col. 4, ln. 5-20, Wirtzfeld). The disclosed stimulation catheter is considered to anticipate the claimed coupling module

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because both devices define a lumen between the modules and permits the motion of the two modules along at least one axis of motion.

With reference to claims 8 and 22 Wirtzfeld is considered to disclose a coupling module that permits motion of the two modules along at least two axes of motion (see col. 4, ln. 5-30, fig. 1, Wirtzfeld). The disclosed stimulation catheter lead is considered to anticipate the two axes of motion because the stimulation catheter lead has a permissible motion that is both horizontal and vertical.

Referring to claim 23, Wirtzfeld is considered to disclose at least one of the two modules comprising a control module containing electronic components (see col. 4, ln. 5-10, Wirtzfeld). The disclosed electronic circuit component is considered to anticipate the claimed electronic component because both devices are associated with the electrical functions of implantable medical devices.

With reference to claims 11, 14, and 15 Wirtzfeld is considered to disclose a coupling module of a circular cross-sectional shape, a semi-circular cross-sectional shape and a rectangular cross-sectional shape (see col. 4, ln. 5-15, Wirtzfeld).

Referring to claim 17, Wirtzfeld is considered to disclose a coupling module made of metal (see col. 4, ln. 30-40, Wirtzfeld). The disclosed metallic element is considered to anticipate the claimed metal module because both configurations enable communication between the two modules.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 9-10 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Wirtzfeld in view of Bradley. Wirtzfeld is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed at least two lumens. Bradley is considered to disclose multiple lumens (see col. 3, ln. 1-20, Bradley). It would have been obvious to one of ordinary skill in the art to combine the teachings of Wirtzfeld with Bradley for the purpose of providing independent interconnection paths that are isolated and separate from each other.

Claim 6 is rejected under 35 U.S.C. §103(a) as being unpatentable over Wirtzfeld in view of Reischl. Wirtzfeld is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed IMD thickness. However, Reischl discloses the smallest dimension of its housing to be between 4 millimeters and 8 millimeters (see col. 2, ln. 25-30, Reischl). It would have been obvious to one of ordinary skill in the art to combine the teachings of Wirtzfeld with Reischl for the purpose of reducing the size of the implantable medical device and reducing limits on the locations within the human body in which the IMD can be practically implanted.

Claim 13 is rejected under 35 U.S.C. §103(a) as being unpatentable over Wirtzfeld in view of Schroeppel. Wirtzfeld is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed bellows section of the coupling module. However, Schroeppel is considered to disclose a bellows hinge (see col. 5, ln. 15-20, Schroeppel). It would have been obvious to one of ordinary skill in the art to combine the teachings of Wirtzfeld with those of Schroeppel for the purpose of enhancing the flexibility of the coupling module or catheter lumen.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/731,638. The two modules of the claimed application possess an identical housing to that of the copending application. Although the conflicting claims are not identical, they are not patentably distinct

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from each other because it would have been obvious to one of ordinary skill in the art to provide an implantable medical device for implantation in the head of a patient with variations of a first and second module including a flexible overmold to cover the modules.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory



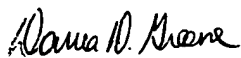
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action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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